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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,937

03/22/2006

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23373 7590 09/16/2008  
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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,937	<b>Applicant(s)</b> KUSUDA ET AL.	
	<b>Examiner</b> Erich A. Leeser	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,12 and 13 is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to Applicant's submission dated August 6, 2008, in which Applicant amended claims 1-6 and 9-10, added claims 12-13, and cancelled claims 7-8 and 11. Claims 1-6, 9-10, and 12-13 are currently pending and under examination in the instant application.

#### ***Claim Rejections - 35 USC § 112***

Examiner previously rejected claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Based on Applicant's claim amendments, Applicant has overcome this rejection.

Examiner previously rejected claims 1-10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. Based on Applicant's claim amendments, Applicant has overcome this rejection.

Examiner previously rejected claims 1-10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making prodrugs of the claimed compounds. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art of medicinal chemistry to use the invention. Based on Applicant's claim amendments, Applicant has overcome this rejection.

Art Unit: 1624

Examiner previously rejected claims 6-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compound to treat any and all known or unknown PPAR-mediated diseases. While enabling for the PPAR $\delta$ -mediated disease hyperlipidemia, the specification is insufficient to enable other diseases mediated by PPAR $\delta$  other than hyperlipidemia. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Based on Applicant's argument of record, Examiner withdraws this rejection with regards to adiposity, but maintains the rejection with regards to all other PPAR-mediated diseases (besides, of course, the previously allowable hyperlipidemia).

Examiner previously rejected claims 6-10 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

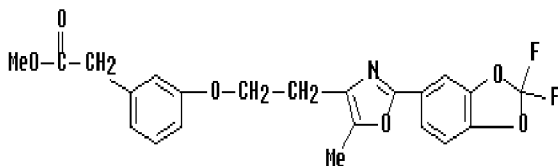
Based on Applicant's claim amendments, however, Applicant has overcome this rejection.

### ***Claim Rejections - 35 USC § 102***

Examiner previously rejected claims 1-2, 4, and 5 under 35 U.S.C. 102(b) as being anticipated by Tajima et al., WO 9946232.

Art Unit: 1624

Even after Applicant's claim amendments, the compound: 3-[2-[2-(2,2-difluoro-1,3-benzodioxol-5-yl)-5-methyl-4-oxazolyl]ethoxy]-methyl ester benzenecetic acid,



still anticipates the instant claims. As such, Examiner maintains the rejection with regards to claim 1 and 5, but withdraws the rejection with regards to claims 2 and 4.

Examiner previously rejected claims 1 and 5 under 35 U.S.C. 102(b) as being anticipated by Brooks et al., WO 2001016120.

Based on Applicant's claim amendments, however, Applicant has overcome this rejection.

Examiner previously rejected claims 1 and 5 under 35 U.S.C. 102(b) as being anticipated by Cheng et al., WO 2002096358.

Based on Applicant's claim amendments, however, Applicant has overcome this rejection.

Examiner previously rejected claims 1-2, and 4-5 under 35 U.S.C. 102(e) as being anticipated by Conner et al., WO 2003072102.

Based on Applicant's claim amendments, however, Applicant has overcome this rejection.

***Claim Rejections - 35 USC § 103***

Examiner previously rejected claims 1-2 and 5 under 103(a) as being unpatentable over Conner et al., WO 2003072100.

Based on Applicant's claim amendments, however, Applicant has overcome this rejection.

***Claim Objections***

Claims 2-4, 6 and 9 are objected to as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

***Allowable Subject Matter***

Claims 10, 12 and 13 are patentable over Tajima et al., WO 9946232. The reference teaches the compound 3-[2-[2-(2,2-difluoro-1,3-benzodioxol-5-yl)-5-methyl-4-oxazolyl]ethoxy]-methyl ester benzeneacetic acid. The difference between the instant compounds of these claims and 3-[2-[2-(2,2-difluoro-1,3-benzodioxol-5-yl)-5-methyl-4-oxazolyl]ethoxy]-methyl ester benzeneacetic acid is that the phenyl of the compounds of these claims are additionally methylated or halogenated, whereas 3-[2-[2-(2,2-difluoro-1,3-benzodioxol-5-yl)-5-methyl-4-oxazolyl]ethoxy]-methyl ester benzeneacetic acid is only mono-substituted. Therefore, the claims are free of prior art.

Art Unit: 1624

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

**/James O. Wilson/**

**Supervisory Patent Examiner, Art Unit 1624**

**Erich A. Leeser**

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